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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,916	10/10/2001	Peter M. Thule	US 1292/01 (VA)	4645

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Law Office - Dinesh Agarwal, P.C.
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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,916	THULE, PETER M.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 1/26/05. The amendment filed 1/26/05 is acknowledged. The amendment has been entered. Claims 1-15 and 17-21 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Election/Restrictions

This application contains claims 17-21 drawn to an invention nonelected with traverse in the paper filed 4/21/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 1/26/05 is sufficient to overcome the rejection of claims 1-5 under 35 USC 102 (a) based upon the disclosure of the Gene Therapy (2000) reference of Thule et al.

Therefore, the rejection of claims 1-15 under 35 USC 102(a) has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Diabetes May 1999, supplement—cited in IDS).

The instant claims are drawn to an insulin regulator construct comprising a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter wherein glucose increases the expression of a sequence operably linked to the construct and wherein insulin suppresses the expression of a sequence operably linked to the construct. It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/(GIRE)₃BP-1 2xfur (which comprises an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

Thule teaches an adenoviral vector comprising all of the claimed elements, and also named the vector Ad/(GIRE)₃BP-1 2xfur (e.g., see abstract). As such, Thule clearly anticipates the insulin regulator construct claimed in claims 1-15.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting June 9-13, 1999—cited in IDS).

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The instant claims are drawn to an insulin regulator construct comprising a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter wherein glucose increases the expression of a sequence operably linked to the construct and wherein insulin suppresses the expression of a sequence operably linked to the construct. It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/(GIRE)₃BP-1 2xfur (which comprises an adenoviral vector comprising 3 GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

Thule teaches an adenoviral vector comprising all of the claimed elements, and also named the vector Ad/(GIRE)₃BP-1 2xfur (e.g., see abstract). As such, Thule clearly anticipates the insulin regulator construct claimed in claims 1-15.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Thule et al (Abstract from meeting June , 1998—cited in IDS).

The instant claims are drawn to an insulin regulator construct comprising a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter wherein glucose increases the expression of a sequence operably linked to the construct and wherein insulin suppresses the expression of a sequence operably linked to the construct. It is noted that the specification describes a construct comprising all of the elements in an adenoviral vector and names the vector Ad/(GIRE)₃BP-1 2xfur (which comprises an adenoviral vector comprising 3

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GIREs, the insulin sensitive element of IGFBP-1 operably linked to a sequence encoding a proinsulin molecule).

Thus, Thule teaches an adenoviral vector comprising all of the claimed elements, and also named the vector Ad/(GIRE)₃BP-1 2xfur (e.g., see abstract). As such, Thule clearly anticipates the insulin regulator construct claimed in claims 1-15.

Response to Arguments

Applicant's arguments filed 1/26/05 have been fully considered.

With respect to the rejection(s) of claim 16, it is noted that claim 16 has been cancelled. As such the rejection of claim 16 are now moot.

With respect to the rejection of claims 1-15 under 35 USC 112, 1st paragraph, 325 USC 12, 2nd paragraph, the rejections have been withdrawn in view of the amendment to the claims and Applicants arguments.

With respect to the rejection of claims under 35 USC 102(a), the rejection has been withdrawn in view of the Declaration filed under 37 CFR 1.132, as indicated above.

With respect to the rejection of claims 1-15 under 35 USC 102(b), Applicant's arguments filed 1/26/05 have been fully considered but they are not persuasive.

Applicants argue that independent Claim 9 is directed to an insulin regulator construct comprising a nucleotide sequence set forth in one of SEQ ID NOs: 3-6, and particularly to the elected species of SEQ ID NO: 5. Applicant respectfully submitted that none of the Thulé publications cited by the Examiner to reject Claims 1-15 under 35 U.S.C. 102(b) discloses the

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sequences of Claim 9. Therefore, Applicant asserts that Claim 1-15 are not anticipated by any of the Thulé publications.

In response, it is respectfully pointed out that the Thule references relied on for the 102(b) rejections do teach adenoviral vectors that comprise all of the structural elements encompassed by the claims. Specifically the Thule references teach a vector comprising a GIRE of the L-PK gene promoter and an insulin sensitive element of the IGFBP-1 basal promoter wherein glucose increases the expression of a sequence operably linked to the construct and wherein insulin suppresses the expression of a sequence operably linked to the construct. Furthermore, the instant specification names the vector encompassed by the claims as Ad/(GIRE)₃BP-1 (e.g., see page 8 of the specification and the “Animals Studies” disclosed on pages 53-54), which is the vector named in the Thule references.

Therefore, ABSENT EVIDENCE TO THE CONTRARY, the Ad/(GIRE)₃BP-1 2xfur vector that expresses the insulin transgene taught by the Thule references is the same Ad/(GIRE)₃BP-1 2xfur vector that is claimed in claims 1-15.

Applicant is reminded that MPEP 2112.01 teaches “Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). ‘When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.’”

Therefore, Applicants arguments are not persuasive.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER